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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,780	02/10/2004	Keren I. Hulkower	06244.00002	9361
22908	7590	10/06/2004	EXAMINER	
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,780

Applicant(s)

HULKOWER ET AL.

Examiner

David J Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-136 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 53-56, 69-89 and 121-124, drawn to devices comprising analyte-specific compound that produces a detectable compound in combination with a substrate, classified in 435/188.5, for example.
- II. Claims 22-31, 39-40, 57-58, 90-99, 107-108 and 125-126, drawn to devices comprising analyte-specific compound that chemically couples to analyte, classified in 435/7.72, for example.
- III. Claims 32-34, 41-42, 59-60, 100-102, 109-110 and 127-128, drawn to devices comprising analyte-specific compound conjugated to an enzyme, classified in 435/7.92, for example.
- IV. Claims 35-37, 43-44, 61-62, 103-105, 111-112 and 129-130, drawn to devices, comprising non-analyte specific compound, classified in 435/7.93, for example.
- V. Claims 38, 45-46, 63-64, 106, 113-114 and 131-132 drawn to devices comprising a tracer, classified in 435/7.7, for example.
- VI. Claims 47 and 115, drawn to methods comprising the step of producing a detectable compound by exposing an analyte-specific compound to an analyte, classified in 435/7.8, for example.
- VII. Claims 48 and 116, drawn to methods comprising the step of producing a detectable compound in combination with a given substrate, classified in 435/287.2, for example.
- VIII. Claims 49-50, 65-66, 117-118, 133-134, drawn to methods comprising the step of exposing an analyte to a conjugate comprising an analyte-specific compound conjugated to an enzyme, classified in 424/134.1, for example.
- IX. Claims 51-52, 67-68, 119-120, 135-136, drawn to methods comprising the step of exposing an analyte-specific compound to a conjugate comprising an enzyme and a non-analyte specific compound, classified in 435/7.95, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

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MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires an analyte-specific compound that produces a detectable compound in combination with a substrate, while Invention II requires an analyte-specific compound that chemically couples to analyte.

Inventions I and III are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires an analyte-specific compound that produces a detectable compound in combination with a substrate, while Invention III requires an analyte-specific compound conjugated to an enzyme.

Inventions I and IV are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires an analyte-specific compound that produces a detectable compound in combination with a substrate, while Invention IV requires a non-analyte specific compound.

Inventions I and V are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

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MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention I requires an analyte-specific compound that produces a detectable compound in combination with a substrate, while Invention V requires a tracer.

Inventions II and III are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention II requires an analyte-specific compound that chemically couples to analyte, while Invention III requires an analyte-specific compound conjugated to an enzyme.

Inventions II and IV are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention II requires an analyte-specific compound that chemically couples to analyte, while Invention IV requires a non-analyte specific compound.

Inventions II and V are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention II requires an analyte-specific compound that chemically couples to analyte, while Invention V requires a tracer.

Inventions III and IV are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention III requires an analyte-specific compound conjugated to an enzyme, while Invention IV requires a non-analyte specific compound.

Inventions III and V are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention III requires an analyte-specific compound conjugated to an enzyme, while Invention V requires a tracer.

Inventions IV and V are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention IV requires a non-analyte specific compound, while Invention V requires a tracer.

Inventions (I, II, III, IV or V) and (VI, VII, VIII or IX) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention (I, II or III) can be used in a materially different process, such as a photodynamic therapeutic process.

Inventions VI and VII are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VI requires the step of producing a detectable compound by exposing an analyte-specific compound to an analyte, while Invention VII requires the step of producing a detectable compound in combination with a given substrate.

Inventions VI and VIII are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VI requires the step of producing a detectable compound by exposing an analyte-specific compound to an analyte, while Invention VIII requires the step of exposing an analyte to a conjugate comprising an analyte-specific compound conjugated to an enzyme.

Inventions VI and IX are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

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MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VI requires the step of producing a detectable compound by exposing an analyte-specific compound to an analyte, while Invention IX requires the step of exposing an analyte-specific compound to a conjugate comprising an enzyme and a non-analyte specific compound.

Inventions VII and VIII are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VII requires the step of producing a detectable compound in combination with a given substrate, while Invention VIII requires the step of exposing an analyte to a conjugate comprising an analyte-specific compound conjugated to an enzyme.

Inventions VII and IX are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VII requires the step of producing a detectable compound in combination with a given substrate, while Invention IX requires the step of exposing an analyte-specific compound to a conjugate comprising an enzyme and a non-analyte specific compound.

Inventions VIII and IX are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and

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they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because Invention VIII requires the step of exposing an analyte to a conjugate comprising an analyte-specific compound conjugated to an enzyme, while Invention IX requires the step of exposing an analyte-specific compound to a conjugate comprising an enzyme and a non-analyte specific compound.

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If Applicants elect Invention I, then the following species elections are required:

A. Select ONE analyte-specific compound group:

1. antibody, protein, peptide; (claims 5, 73)
2. biotin; (claims 5, 73)
3. hapten; (claims 5, 73)
4. drug analyte or drug metabolite; (claims 5, 73)
5. carbohydrate moiety; (claims 5, 73)
6. nucleic acid; (claims 6-7, 20-21, 74-75, 88-89)
7. nucleic acid and protein fusion; (claims 5, 73) OR
8. protein and small organic molecule fusion. (claims 5, 73)

B. Select TWO dyes (claim 18):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphyrinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphyrinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphyrinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxahenyl)porphyrinatozinc(II) [Zn(Si6PP)];
5. 5,10,15,20-Tetraphenyl-21H,23H-porphine [H2TPP];
6. Thymol Blue;
7. Cresol Red;
8. Phenol Red;
9. Bromocresol Purple;
10. Bromocresol Green;
11. Bromothymol Blue;
12. Nitrazine Yellow;

C. Select ONE porphyrin dye (claim 86):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphyrinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphyrinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphyrinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxahenyl)porphyrinatozinc(II) [Zn(Si6PP)]; OR
5. 5,10,15,20-Tetraphenyl-21H,23H-porphine [H2TPP];

If Applicants elect Invention II, then the following species elections are required:

A. Select TWO dyes (claim 40):

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1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphyrinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphyrinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphyrinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)];
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];
6. Thymol Blue;
7. Cresol Red;
8. Phenol Red;
9. Bromocresol Purple;
10. Bromocresol Green;
11. Bromothymol Blue;
12. Nitrazine Yellow;

B. Select ONE porphyrin dye (claim 108):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphyrinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphyrinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphyrinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)]; OR
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];

If Applicants elect Invention III, then the following species elections are required:

A. Select TWO dyes (claim 42):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphyrinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphyrinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphyrinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)];
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];
6. Thymol Blue;
7. Cresol Red;
8. Phenol Red;
9. Bromocresol Purple;
10. Bromocresol Green;
11. Bromothymol Blue;
12. Nitrazine Yellow;

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B. Select ONE porphyrin dye (claim 110):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphirinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphirinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphirinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)]; OR
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];

If Applicants elect Invention IV, then the following species elections are required:

A. Select TWO dyes (claim 44):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphirinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphirinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphirinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)];
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];
6. Thymol Blue;
7. Cresol Red;
8. Phenol Red;
9. Bromocresol Purple;
10. Bromocresol Green;
11. Bromothymol Blue;
12. Nitrazine Yellow;

B. Select ONE porphyrin dye (claim 112):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphirinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphirinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphirinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxaheny)porphyrinatozinc(II) [Zn(Si6PP)]; OR
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];

If Applicants elect Invention V, then the following species elections are required:

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A. Select TWO dyes (claim 46):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphirinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphirinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphirinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxahenyl)porphyrinatozinc(II) [Zn(Si6PP)];
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];
6. Thymol Blue;
7. Cresol Red;
8. Phenol Red;
9. Bromocresol Purple;
10. Bromocresol Green;
11. Bromothymol Blue;
12. Nitrazine Yellow;

B. Select ONE porphyrin dye (claim 114):

1. 2,3,7,8,12,13,17,18,-octafluoro-5,10,15,20-tetrakis (pentafluorophenyl) porphirinatocobalt (II) [Co(F28TPP)];
2. 2,3,7,8,12,13,17,18,-octabromo-5,10,15,20-tetraphenylporphirinatozinc(II) [Zn(Br8TPP)];
3. 5,10,15,20-tetraphenylporphirinatozinc(II) [ZnTPP];
4. 5(phenyl)-10,15,20-trikis(2',6'-disilyloxahenyl)porphyrinatozinc(II) [Zn(Si6PP)]; OR
5. 5,10,15,20-Tetrapheny-21H,23H-porphine [H2TPP];

For example, if Applicants elect Invention I(A1)(B1)(C1), then claims 1-5, 8-19, 53-56, 69-73, 76-87, 121-124 shall be examined. If Applicants elect Invention I(A6)(B1)(C1), then claims 1-21, 53-56, 69-89, 121-124 shall be examined. If Applicants elect Invention V(A1)(B1), then claims 38, 45-46, 63-64, 106, 113-114 and 131-132 shall be examined.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney Robert Resis on or about September 24, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/01/02

djv